



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
RESEARCH AND DEVELOPMENT

AUG 26 2004

DATE:

MEMORANDUM

SUBJECT: Decision Memorandum - New NCER Assistance Agreement

Number: RD831861

Title: Children's Environmental Health Center

Institution: University of Southern California

Principal Investigator: Frank Gilliland, MD, PhD

FROM:

Becki M. Clark, Director

(b) (6)

Environmental Science Research Division (8723F)

National Center for Environmental Research

TO:

John C. Puzak, Acting Director

National Center for Environmental Research (8701F)

I. OBJECTIVES:

The purpose of this action is to request approval of a new grant assistance agreement between the University of Southern California and the U.S. Environmental Protection Agency (EPA).

The proposed project was submitted in response to a joint EPA and National Institute of Environmental Health Sciences (NIEHS) 2003 solicitation for *RFA # ES-03-004* entitled: Centers for Children's Environmental Health Research and Disease Prevention. The Center will be jointly funded and managed by the EPA and the NIEHS.

The Children's Environmental Health Center (CEHC) will apply innovative mechanistic, epidemiologic, and community-based participatory research methods to address concerns regarding the links between air pollution and childhood airway disease in the Los Angeles Basin. University investigators will partner with prominent, respected health advocacy groups to determine if regional ambient air pollutants increase the risk of early life asthma; if children with particular levels of expression or variations of genes are more sensitive to air pollution; and if community-participation enhances scientific approaches and translation of research to better protect children's environmental health. The CEHC will pursue three well-integrated research projects with the aid of three facility cores to achieve their goals.

II. STATUTORY AUTHORITY/ENVIRONMENTAL RESULTS:

The statutory authority for funding this assistance agreement is found in:

Clean Air Act—Section 103.

Section 103 authorizes the EPA to make grants to institutions for research, investigations, experiments, demonstrations, surveys and studies relating to the causes, effects (including health and welfare effects), extent, prevention and control of air pollution. This grant supports Goal 4, Healthy Communities and Ecosystems, of EPA's Strategic Plan. The Program Results Code (PRC) assigned to the funding of this project is consistent with that goal. Central to the CEHC's objectives is the testing of hypotheses examining the influence of criteria oxidants and nitrosants, such as ozone, nitrous oxide, nitrous dioxide, and reactive organic compounds--resulting largely from vehicular exhaust--on children's health. Specifically, the proposal will address the themes of air pollution, childhood airway disease, and mechanisms of susceptibility.

III. DELEGATION OF AUTHORITY NUMBER: ORD 1-98

IV. JUSTIFICATION FOR SELECTION OF ASSISTANCE AGREEMENT:

The primary purpose of this project is to support the accomplishment of a public purpose to promote research in the subject area rather than to acquire property or services for the EPA. This agreement has been reviewed relative to the guidance in EPA Order 5700.1, "Policy for Distinguishing Between Assistance and Acquisition," and is appropriate for assistance based on the criteria and examples of the Order.

This project offers a unique opportunity for Los Angeles area researchers to further advance and specify their inquiry into regional childhood airway disease and prevention, building on over five years of previous research and outreach. Both the scientific approaches and translation methods developed for the purposes of this research will not only be of primary importance to Los Angeles area residents, but will also contribute significantly to the overall body of science for asthma etiology, urban air toxics exposure, and asthma management.

The EPA will not be substantially involved in this project. Therefore, a grant has been chosen as the appropriate type of assistance.

V. EXPLANATION OF ANY APPARENT DUPLICATIVE OR EXCESSIVE EFFORTS:

To the best of my knowledge, this proposal does not duplicate research efforts that have been performed in-house or extramurally by the EPA or by any other sources.

VI. REVIEWS:

The application was evaluated by an ad-hoc technical peer review group consisting of experts in the relevant scientific disciplines. This application was reviewed by at least two external reviewers and one internal reviewer. All reviewers were required to sign a statement that they

had no known conflict of interest.

The peer reviews were based strictly on the information provided in the proposals. Reviewers were directed to evaluate the merit of the proposals by addressing specific scientific and technical issues. These issues include: the scientific merit, quality and originality of the proposed work; the qualifications of the Principal Investigator(s) and other key personnel assigned to the project; the adequacy of the quality assurance narrative; and the responsiveness of the proposed research to needs identified in the RFA. Based on these criteria, the reviewers determined that this proposal was meritorious and recommended that it be considered for funding. A summary of the peer review group's comments, discussion, and recommendations is included in the package. Complete records of all the external review documentation are available in NCER.

VII. RECONCILIATION OF ANY CONTRARY REVIEWS:

The reviewers favored the proposal and recommended funding, but suggested modifications or requested additional information related to the proposal. These comments and suggestions were provided to the Principal Investigator who developed an acceptable response. Both the reviewers' comments and the Principal Investigator's response are included in the package.

In addition to the external peer review, an internal review was conducted by an appropriate team of experts from within the EPA. The EPA team conducted a programmatic review of each proposal recommended by the peer review group to assure a balanced research portfolio for the Agency and to assess each proposal's complementarity with intramural programs. The team made recommendations to the Decision Official.

VIII. COMPETITION:

This application is the result of a competitive solicitation.

IX. PROGRAM TERMS AND CONDITIONS:

A copy of the NCER standard Center terms and conditions, modified for this award, is attached and will be included as part of the final grant award.

X. SOLICITED / UNSOLICITED RESEARCH:

This proposal was solicited.

XI. JUSTIFICATION FOR MIXING APPROPRIATIONS:

This agreement will not entail mixing appropriations.

XII. QUALITY ASSURANCE:

The quality assurance statements have been reviewed by the Project Officer who deemed them

adequate for conditional approval. However, more detailed statements (i.e., a Quality Management Plan and an integrated Quality Assurance Project Plan) must be submitted within 60 days of the award acceptance date and approved by the Project Officer as meeting the requirements of 40 C.F.R. Part 30. A programmatic condition to this effect will be included in the award document.

XIII. PREAWARD COSTS APPROVAL:

Approval of pre-award costs is recommended. This competitive award allows for the continuation of the CEHC, which began in 1998. Pre-award costs are necessary to ensure continuity between the work conducted under the previous grant for this Center and this award. Work has already begun on this grant. Most of the work involves the use of human subjects which could not be delayed. A start date of November 1, 2003 is recommended.

XIV. FOREIGN ACTIVITIES APPROVAL:

Not applicable.

XV. HUMAN SUBJECTS:

This study will involve the use of human subjects but the investigators have not finalized plans for the use of human subjects that would normally be set forth in the application or proposal. Therefore, the study has been approved under Section 118 of 40 CFR 26. A copy of this approval is included in the package. Section 118 of 40 CFR 26 states that under certain circumstances "applications need not be reviewed by an institutional review board (IRB) before an award may be made. However, except for research exempted or waived under Sec. 26.101 (b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency." A term and condition has been added to this award requiring the applicant to provide proof of the institution's Human Subjects IRB approval and copies of all other documentation forwarded to the IRB for its approval to the Project Officer prior to the enrollment or use of any human subject. The Project Officer will forward the documentation to EPA's Human Subjects Research Review Official (HSRRO) for review and approval. The requirements of EPA Order 1000.17, Change A1, Policy and Procedures on Protection of Human Research Subjects in EPA Conducted or Supported Research, have been satisfied.

Additionally, since this research project involves the use of children as subjects, the researchers must follow Subpart D, of 45 CFR Part 46, "Additional DHHS Protections for Children Involved as Subjects in Research." A term and condition requiring adherence to this requirement is included in the package.

XVI. WORKSHOPS AND CONFERENCES:

The proposal states that a workshop or conference may be held. The six Grants Administration Division (GAD) questions regarding this activity are addressed in an attachment.

XVII. PROGRAM INCOME:

If program income is generated under this award, the Center will have the choice of allocating program income by adding to funds committed to the agreement (i.e., roll income back into the research effort), and/or use it to finance the non-Federal share of the project.

XVIII. PROGRAM RESULTS CODE:

See attached "Substitute OMIS Information Sheet." The OMIS information sheet contains the ORD program results code, task, and other project identifiers for this award.

XIX. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:

The CFDA number is 66.509.

XX. PAPERWORK REDUCTION ACT:

The Paperwork Reduction Act does not apply. The collection of information is not being conducted at the specific request of the Agency and the terms and conditions of this grant do not require specific approval by EPA of the collection of information or collection procedures.

XXI. RECOMMENDATION:

The project is recommended for funding based on the quality of the proposal, the relevancy of the research and the excellent qualifications of the applicant, and its appropriateness as an assistance award. I also recommend the following:

1. Funding from the EPA at the proposed level.
2. A 5-year project and budget period.
3. A total EPA and NIEHS combined budget of \$7,181,692 for the project period.
4. A total EPA budget of \$3,590,846 for the project period.
5. A one year partial EPA funding of \$769,302 for this action.
6. Nigel Fields will serve as Project Officer for this award and has completed the Project Officer's Course for Assistance Management.

Concur: ✓ yes no



John C. Puzak, Acting Director
National Center for Environmental Research

9-8-2-2004
Date

XXII. SENIOR RESOURCE OFFICIAL'S APPROVAL:
This package requires SRO approval.



for Signature of Director, Office of Resources
Management and Administration

9/14/04
Date



Signature of Senior Resource Official

9/15/04
Date